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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,365	03/05/2007	Wolfgang Richter	65174(52171)	9460
21874	7590	10/30/2008		
EDWARDS ANGELL PALMER & DODGE LLP				
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EXAMINER				
YOUNG, SHAWQUITA				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
10/30/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/573,365

**Applicant(s)**

RICHTER ET AL.

**Examiner**

SHAWQUIA YOUNG

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/30/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-31 is/are pending in the application.
- 4a) Of the above claim(s) 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SG/08)  
Paper No(s)/Mail Date 3/23/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 15-31 are currently pending in the instant application. Applicants have cancelled claims 1-14 and added new claims 15-31 in a preliminary amendment.

#### **I. *Priority***

The instant application is a 371 of PCT/EP04/10820, filed on September 27, 2004 and claims benefit of Foreign Application GERMANY 103 44 882.9, filed on September 26, 2003. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on September 26, 2003. It is noted, however, that applicant has not filed a certified copy of the GERMANY 103 44 882.9 application as required by 35 U.S.C. 119(b).

#### **II. *Information Disclosure Statement***

The information disclosure statement (IDS) submitted on March 23, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

#### **III. *Restriction/Election***

##### **A. *Election: Applicant's Response***

Applicants' election with traverse of Group I in the reply filed on September 30, 2008 is acknowledged. The traversal is on the ground(s) that: (1) that the claims of Groups I through VI are linked so as to form a single general inventive

concept.

All of the Applicants' arguments and exhibits enclosed have been considered but have not been found persuasive. It is pointed out that the restriction requirement is made under 35 U.S.C. 121. 35 U.S.C. 121 gives the Commissioner (Director) the authority to restrict applications to several claimed inventions when those inventions are found to be independent and distinct. The Examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted the claimed subject matter accordingly.

Applicants argue that all of the groups are linked by a common inventive concept. However, the Examiner wants to point out that the special technical feature in the claims have to provide a contribution over the art and it does not as discussed in the Restriction Requirement. The Restriction Requirement detailed the reasons for restriction between the groups. Different search considerations are involved (i.e., class/subclass searches, databases searches, etc.) for each of the groups listed. The inventions are classified into classes 514, 544, 546, 548 and 549. However, each Class 514, 544, 546 and 548 encompasses numerous patents and published applications. For instance, Class 514 contained 165,171 patents and published applications. Therefore it would constitute a burden on the Examiner and the Patent Office's resources to examine the instant application in its entirety.

Subject matter not encompassed by elected Group I are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions.

#### IV. Rejections

##### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicants have failed to disclose a clear description in the specification of any method of making the claimed compounds which is a requirement under 35 USC 112, first paragraph.

Claims 15-28 are rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the enablement requirement. The specification does not provide sufficient guidance nor does it enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first

paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case

***The nature of the invention***

The nature of the invention is a compound of formula I.

***The amount of direction or guidance present and the presence or absence of working examples***

There is no direction or guidance present in the specification or clear working examples present in the specification that shows how to prepare Applicants' instantly claimed compounds.

***The breadth of the claims***

The breadth of the claims is a compound, or pharmacologically acceptable salt, solvate, hydrate or a pharmacologically acceptable formulation thereof.

***The quantity of experimentation needed and the level of the skill in the art***

While the level of the skill in the pharmaceutical art is high, the quantity of

experimentation needed is undue experimentation. One of skill in the art would need to prepare compounds with various solvents without any direction as to how to make Applicants' "novel" compounds as well as salts, solvates, hydrates and a formulation thereof.

The level of skill in the art is high without showing or guidance as to how to make the compounds of formula (I) it would require undue experimentation to figure out the solvents, temperatures and reaction times that would provide Applicants' instant compounds.

#### **V. *Objections***

##### ***Specification***

The disclosure is objected to because of the following informalities: the specification does not end in a period.

Appropriate correction is required.

##### ***Oath/Declaration***

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

#### **VI. *Conclusion***

Any inquiry concerning this communication or earlier communications from

the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/  
Examiner, Art Unit 1626

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626